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Independent Analysis

Independent Analysis of Clinical Trial Data: GS1 Continuous Glucose Monitoring System (CGMS) in Pediatric Diabetes Management

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Abstract

Background: Diabetes mellitus poses significant challenges in pediatric populations, necessitating advanced glycemic monitoring technologies. This study presents an independent analysis of the GS1 Continuous Glucose Monitoring System (CGMS), originally developed by Shenzhen SiSensing Co., Ltd., and provided by its Turkish partner, BMED Pharmaceuticals. The analysis evaluates the efficacy, safety, and usability of the GS1 CGMS in pediatric patients aged 3 to under 18 years with diabetes mellitus.

Methods: This multicenter, prospective trial included 81 pediatric participants across three clinical centers in China: Beijing Children's Hospital, Capital Medical University (Center 01); Shenzhen Children's Hospital (Center 02); and Fujian Medical University Union Hospital (Center 03). Participants underwent 14 days of CGMS monitoring, with venous blood glucose measurements as reference. Key metrics included concordance rates within the 20/20% error range, Clarke and Consensus Error Grid analyses, and Mean Absolute Relative Difference (MARD%). Safety and usability were assessed through adverse event monitoring and participant feedback.

Results: A total of 79 participants completed the trial, achieving a 97.5% completion rate. Concordance rates were 93.9% across all glycemic ranges, surpassing predefined thresholds. Sensitivity and specificity for hypoglycemia detection were 97.6% and 87.3%, respectively, while hyperglycemia detection achieved 89.8% sensitivity and 97.0% specificity. The MARD% was 8.7%, consistently below the target of 18%. Usability scores averaged 95.3 ± 7.59, reflecting high satisfaction. Device-related adverse events, such as mild skin irritation, were self-limiting, and no serious adverse events were reported.

Conclusion: This independent analysis demonstrated that the GS1 CGMS offers high accuracy, safety, and usability in pediatric glycemic monitoring. These findings support its broader application in routine pediatric diabetes care. Future studies should explore long-term efficacy and comparative evaluations with other CGMS technologies.

Keywords Independent analysis, Continuous Glucose Monitoring (CGM), GS1 CGMS, Pediatric diabetes patients

Introduction

Diabetes mellitus has emerged as a significant global public health issue, posing critical challenges to individual health and societal well-being. The disease is associated with severe complications, including coronary heart disease, cerebrovascular disease, nephropathy, blindness, and limb amputation, resulting in substantial health losses and economic burdens on healthcare systems worldwide. The 10th edition of the International Diabetes Federation (IDF) Diabetes Atlas highlights the urgency of this health crisis, reporting that over 6.7 million people aged 20–79 died from diabetes-related complications in 2021, with associated medical expenditures nearing $1 trillion USD[1,2].

Globally, the prevalence of diabetes mellitus was estimated at 537 million people in 2021, a figure projected to rise to 643 million by 2030 and 783 million by 2045. Among children, the burden is particularly severe, with over 1.2 million children aged 0–19 years living with type 1 diabetes mellitus (T1DM) in 2021, and 108,200 new cases diagnosed annually in children under 15 years old. This burden is disproportionately high in countries like India, the United States, Brazil, and China. T1DM accounts for approximately 90% of diabetes cases in children, with early onset linked to a higher risk of chronic complications and reduced life expectancy[3,4].

Effective glycemic control is critical for reducing diabetes-related complications. However, traditional methods such as self-monitoring of blood glucose (SMBG) and glycated hemoglobin (HbA1c) have notable limitations. HbA1c reflects average glucose levels over months but does not capture daily fluctuations or hypoglycemic episodes. Similarly, SMBG provides intermittent data, often missing critical variations in

glucose levels. These limitations underscore the need for more advanced monitoring methods[5,6].

Continuous Glucose Monitoring (CGM) systems have revolutionized diabetes care by providing real-time insights into glucose trends and variability. These systems are particularly effective in identifying asymptomatic hypoglycemia and improving glycemic control. The GS1 CGMS, developed by Shenzhen SiSensing Co., Ltd., has demonstrated efficacy and safety in adult populations and is approved for monitoring interstitial fluid glucose levels. However, its applicability in pediatric populations remains to be thoroughly evaluated[7,8].

This study represents an independent analysis of clinical trial data shared by Shenzhen SiSensing Co., Ltd. and its Turkish partner, BMED Pharmaceuticals. The aim was to expand the application of the GS1 CGMS to pediatric patients aged 3 to under 18 years. The trial evaluates the system's performance, focusing on concordance with venous blood glucose measurements, Clarke and Consensus Error Grid analyses, and Mean Absolute Relative Difference (MARD). Additionally, adverse events and concomitant medication data were recorded to assess the device's safety profile. By addressing these objectives, the study seeks to contribute to the broader adoption of CGM systems in pediatric diabetes management, ultimately supporting better clinical outcomes for young patients.[9,10].

Material and Methods

Study Design

This was a prospective, multicenter, single-group target value trial designed to evaluate the performance, safety, and usability of the GS1 Continuous Glucose Monitoring System (CGMS) in pediatric patients aged 3 to under 18 years with diabetes mellitus. The trial spanned from July 11, 2023, to November 17, 2023, and was conducted across three clinical centers in China:

Beijing Children's Hospital, Capital Medical University (Center 01), Shenzhen Children's Hospital (Center 02), and Fujian Medical University Union Hospital (Center 03).

The trial was sponsored by Shenzhen SiSensing Co., Ltd. (Protocol No. SS-CTP-GS1-0002, Version V1.0, dated February 24, 2023). This independent analysis was conducted using clinical trial data shared by Shenzhen SiSensing Co., Ltd., and its Turkish partner, BMED Pharmaceuticals. The study adhered to the principles of the Declaration of Helsinki, Good Clinical Practice (GCP), and local regulatory requirements. The trial protocol was submitted to and approved by the Ethics Committees of Beijing Children's Hospital, Capital Medical University (approval date: April 14, 2023), Shenzhen Children's Hospital (approval date: July 14, 2023), and Fujian Medical University Union Hospital (approval date: June 30, 2023). No revisions occurred during the clinical trial.

Trial Flowchart

The clinical trial followed a standardized flowchart:

1. Signing of informed consent form (ICF).
2. Medical history collection.
3. Physical examination.
4. Routine blood and glycated hemoglobin (HbA1c) tests.
5. Coagulation function evaluation.
6. Pregnancy testing (if applicable).
7. Sensor application.
8. CGMS usage.
9. Venous blood glucose testing.
10. Sensor removal.
11. Skin assessment.
12. Completion of usability questionnaires.
13. Recording of adverse events (AEs) and concomitant medication use.

Participants

Participants were enrolled based on the following criteria:

Inclusion Criteria:

- Aged 3 to under 18 years.
- Clinical diagnosis of diabetes mellitus.
- Willingness to wear the device and comply with the study protocol.

Exclusion Criteria:

- Severe hypoglycemia within the past six months.
- Significant skin conditions at sensor application sites.
- Abnormal coagulation function, anemia, or pregnancy.
- Recent participation in another clinical trial.
- Requirement for MRI or CT scans during the study.

Withdrawal Criteria:

Participants were allowed to withdraw at any point, with reasons documented.

Sample Size

The study initially planned to enroll 60 participants to meet the statistical requirements for the primary and secondary evaluation indicators. Considering potential dropouts, the sample size was increased to 81 participants. Ultimately, 79 participants completed the trial, yielding a 97.5% completion rate.

Trial Procedures

Participants underwent a 7-day screening and enrollment period followed by a 14-day sensor wear period. Venous blood glucose testing was performed at predetermined intervals to assess CGMS accuracy. The device was applied to the upper arm, and skin assessments were conducted post-wear. Usability questionnaires were completed to evaluate the device's comfort and ease of use.

Trial Device

The GS1 CGMS consisted of a sensor kit and CGMS software (Version 02). Venous blood glucose measurements using the EKF Glucose/Lactate Analyzer served as the reference standard.

Primary Evaluation Indicators

1. Concordance of CGMS readings within a 20/20% error margin of reference values.
2. Proportion of measurement points in Clarke and Consensus Error Grid Analysis zones A and B.
3. Mean Absolute Relative Difference (MARD%).

Safety Assessment

Adverse events were recorded and categorized by severity and relationship to the trial device. The incidence and management of these events were analyzed to ensure a comprehensive evaluation of the device's safety profile.

Data Analysis

All statistical analyses were conducted using SAS® software (version 9.4). Quantitative variables were summarized using descriptive statistics, and hypothesis testing was performed with a two-sided significance level of $p \leq 0.05$.

Results

Participant Enrollment and Demographics

A total of 81 participants were enrolled across three clinical centers:

- Beijing Children's Hospital, Capital Medical University (Center 01, n=40),
- Shenzhen Children's Hospital (Center 02, n=23),
- Fujian Medical University Union Hospital (Center 03, n=18).

Of these, 79 participants successfully completed the trial, yielding a high completion rate of 97.5%. The 2.5% dropout rate (n=2) was attributed to the voluntary withdrawal of informed consent (n=1) and the lack of valid paired measurement data caused by premature sensor detachment prior to venous blood collection (n=1).

The demographic data of the Full Analysis Set (FAS) revealed:

- **Average Age**: 9.5 ± 4.00 years (range: 3–17 years),
- **Gender Distribution**: 41.3% male, 58.8% female,
- **Ethnicity**: Predominantly Han (92.5%), with other ethnicities accounting for 7.5%.

Educational levels varied:

- 46.3% attended primary school,
- 20.0% were in junior high school,
- 8.8% were in high school,
- 25.0% fell into the "other" educational category.

Participants' average height was 140.53 ± 22.78 cm, and the average weight was 38.02 ± 16.18 kg. Table 1 summarizes these characteristics.

Table 1: Demographic Characteristics of Participants

Parameter	Mean ± SD (Range) / Proportion
Age (years)	9.5 ± 4.00 (3–17)
Gender: Male	41.3%
Gender: Female	58.8%
Han Ethnicity	92.5%
Other Ethnicities	7.5%
Educational Level	Primary (46.3%), Junior High (20.0%), High School (8.8%), Other (25.0%)
Height (cm)	140.53 ± 22.78
Weight (kg)	38.02 ± 16.18

Baseline Glycemic Control Levels

Fasting Blood Glucose:

- Mean: 7.95 ± 3.44 mmol/L,
- Median: 7.25 mmol/L,
- Range: 2.80–17.92 mmol/L.

Clinical Significance:

- 73.8% of participants presented with fasting blood glucose abnormalities of clinical significance,
- 25.0% had normal levels,
- 1.3% displayed abnormalities of no clinical significance.

Glycated Hemoglobin (HbA1c):

- Mean: 7.38 ± 1.40%,
- Median: 7.05%,
- Range: 5.3–11.9%.

Among participants:

- 88.8% showed clinically significant HbA1c abnormalities,
- 11.3% maintained normal HbA1c levels.

Concordance Rates Across Glycemic Ranges

The study collected a total of 1,457 valid paired measurement points, categorized as follows:

- **Low Glycemic Range (<4.4 mmol/L)**:
  - Concordance Rate: 97.4% (188/193),
  - 95% Confidence Interval (CI): 94.1–99.2%.
- **Medium Glycemic Range (4.4–11.1 mmol/L)**:
  - Concordance Rate: 91.3% (747/818),
  - 95% CI: 89.2–93.2%.
- **High Glycemic Range (>11.1 mmol/L)**:
  - Concordance Rate: 97.1% (433/446),
  - 95% CI: 95.1–98.4%.

All concordance rates exceeded the predefined performance thresholds of ≥65% for the point estimate and ≥60% for the lower bound of the 95% CI.

Table 2. Summary of Concordance Rates within 20/20% Error Range by Blood Glucose Range.

Glycemic Range (mmol/L)	Concordance Rate (%)	95% CI
Low (<4.4)	97.4%	94.1%–99.2%
Medium (4.4–11.1)	91.3%	89.2%–93.2%
High (>11.1)	97.1%	95.1%–98.4%

Zone-wise Distribution in Clarke and Consensus Error Grid Analyses

Clarke Error Grid Analysis

The Clarke Error Grid analysis evaluates the clinical significance of glucose readings by categorizing measurement points into specific zones. The distribution of points across zones A, B, C, D, and E for the GS1 CGMS was analyzed by glycemic range:

- **Low Glycemic Range (<4.4 mmol/L):**
  - Zone A: 90.7%
  - Zone B: 7.8%
  - Zone D: 1.6%
  - No points were observed in Zones C or E.
- **Medium Glycemic Range (4.4–11.1 mmol/L):**
  - Zone A: 91.2%
  - Zone B: 8.8%
  - No points were observed in Zones C, D, or E.
- **High Glycemic Range (>11.1 mmol/L):**
  - Zone A: 97.1%
  - Zone B: 2.5%
  - Zone D: 0.4%
  - No points were observed in Zones C or E.

Table 3: Proportion of Measurement Points within Clarke Error Grid Zones A, B, and D by Glycemic Range.

Glycemic Range (mmol/L)	Zone A (%)	Zone B (%)	Zone D (%)	Other Zones (%)
Low (<4.4)	90.7	7.8	1.6	0.0
Medium (4.4–11.1)	91.2	8.8	0.0	0.0
High (>11.1)	97.1	2.5	0.4	0.0

Consensus Error Grid Analysis

The Consensus Error Grid analysis evaluates glucose measurement accuracy based on clinical impact. Across all glycemic ranges, 100% of measurement points fell within Zones A and B:

- **Zone A:** 92.4%

- **Zone B:** 7.6%
- No points were observed in Zones C, D, or E.

These results meet and exceed the predefined performance criteria of ≥95% for the combined proportions of Zones A and B, demonstrating the GS1 CGMS's clinical accuracy and reliability.

Table 4: Consensus Error Grid Analysis Across All Glycemic Ranges

Zone	Proportion of Points (%)
Zone A	92.4
Zone B	7.6
Zones C, D, E	0.0

Sensitivity and Specificity Metrics for Detecting Hypoglycemia and Hyperglycemia

The GS1 CGMS demonstrated strong performance in identifying hyperglycemia and hypoglycemia events. The following metrics were used to evaluate the accuracy of the alerts:

- **Hyperglycemia Alerts:**
  - Sensitivity: 89.8%
  - Specificity: 97.0%
- **Hypoglycemia Alerts:**
  - Sensitivity: 97.6%
  - Specificity: 87.3%

These values highlight the GS1 CGMS's high accuracy, showcasing its effectiveness in real-time detection of critical glycemic events. Metrics such as True Alert Rates (HeTAR/HoTAR), False Alert Rates (HeFAR/HoFAR), Detection Rates (HeDR/HoDR), and Missed Detection Rates (HeMDR/HoMDR) were analyzed to further validate the device's performance.

Table 5: Sensitivity and Specificity Metrics for Glycemic Events

Metric	Hyperglycemia (%)	Hypoglycemia (%)
Sensitivity	89.8	97.6
Specificity	97.0	87.3

Comparison of GS1 CGMS Readings with Venous Blood Glucose Reference Values

A total of 450 measurement points were recorded with glucose concentrations exceeding 11.1 mmol/L. Of these, four data points surpassed the device's upper display limit of 25 mmol/L. These instances did not compromise the device's alerting function, yielding:

- **Hyperglycemia Detection Rate (HeDR):** 97.0%
- **Missed Detection Rate (HeMDR):** 3.0%

Similarly, 205 measurement points were recorded with glucose levels below 4.4 mmol/L. Among these, 12 values fell below the device's lower display range of 2.2 mmol/L, resulting in:

- **Hypoglycemia Detection Rate (HoDR):** 87.3%
- **Missed Detection Rate (HoMDR):** 12.7%

Variability in MARD% Across Participant Subgroups

The Mean Absolute Relative Difference (MARD%) across the full analysis set (FAS) was 8.7% ± 4.02%, significantly below the target threshold of <18%. The upper limit of the 95% confidence interval was 9.6%, remaining well within the protocol-specified limit of <20%. These findings confirm that the MARD% values meet the predefined accuracy standards. Performance stratified by glycemic range and participant subgroups revealed consistent results:

By Glycemic Range:

- **Low Concentration (<4.4 mmol/L):** MARD% = 10.8% ± 6.54% (95% CI upper limit: 13.1%)
- **Medium Concentration (4.4–11.1 mmol/L):** MARD% = 9.6% ± 5.07% (95% CI upper limit: 10.7%)
- **High Concentration (>11.1 mmol/L):** MARD% = 7.4% ± 4.34% (95% CI upper limit: 8.6%)

By Age Group:

- **Under 6 years:** MARD% = 8.5% ± 4.19% (95% CI upper limit: 10.7%)
- **6–13 years:** MARD% = 8.6% ± 4.09% (95% CI upper limit: 9.9%)
- **13–18 years:** MARD% = 9.1% ± 3.91% (95% CI upper limit: 10.9%)

By Clinical Center:

- **Center 01 (Beijing):** MARD% = 9.3% ± 4.43% (95% CI upper limit: 10.7%)
- **Center 02 (Shenzhen):** MARD% = 8.4% ± 3.74% (95% CI upper limit: 10.0%)
- **Center 03 (Fujian):** MARD% = 7.8% ± 3.28% (95% CI upper limit: 9.5%)

Table 6: MARD% by Glycemic Range

Glycemic Range (mmol/L)	MARD% (Mean ± SD)	95% CI Upper Limit
Low (<4.4)	10.8% ± 6.54%	13.1%
Medium (4.4–11.1)	9.6% ± 5.07%	10.7%
High (>11.1)	7.4% ± 4.34%	8.6%

Analysis of Device Reliability Over the 14-Day Wear Period

The stability and performance of the GS1 CGMS were evaluated across various phases of the 14-day wear period. The **Mean Absolute Relative Difference (MARD%)** for the primary sensor exhibited consistent accuracy during these phases:

- **Early (Day 1):** 11.7% ± 4.42%
- **Early-Middle (Days 2–5):** 10.0% ± 4.45%
- **Middle (Days 6–9):** 7.4% ± 2.74%
- **Middle-Late (Days 10–13):** 7.5% ± 3.44%
- **Late (Day 14):** 11.0% ± 5.35%

The **20/20% concordance rates** with venous blood glucose values were as follows:

- Day 1: 86.4%
- Days 2–5: 92.7%
- Days 6–9: 95.3%
- Days 10–13: 95.7%
- Day 14: 92.9%

These findings indicate that the device maintained stable and reliable performance throughout the wear period, consistently exceeding predefined accuracy thresholds.

Failure Rate and Data Interruptions

Sensor inactivation was defined as premature removal or functional failure during the 14-day wear period. A total of **15 out of 160 sensors** (9.4%) were deactivated, distributed across the study days as follows:

- Days 1, 4, 6, 9, and 14: 2 sensors each
- Days 10, 11, and 12: 1 sensor each

Reasons for sensor inactivation included minor skin irritation or voluntary participant withdrawal. Notably one participant withdrew early without any reported device-related reliability issues.

Usability and Comfort: Questionnaire Responses

A detailed usability survey with 20 evaluation items was completed by all **80 participants**. No instances of "Dissatisfied" or "Very Dissatisfied" responses were recorded, and the average usability score was **95.3 ± 7.59 points**, reflecting high user satisfaction.

Specific Findings:

- **Instruction Manual:** Appropriate size and text (99% approval), with 72.5% reporting "Very Satisfied."
- **Sensor Handling:** Ease of wearing (82.5% "Very Satisfied") and removing (80% "Very Satisfied") with no negative feedback.
- **Application Usability:** High satisfaction with brightness (80% "Very Satisfied"), font clarity (78.8%), and glucose curve maps (76.3%).

Subgroup Analysis of Usability Scores by Age Group

Participants in all age groups reported consistently high satisfaction:

- **Under 10 years:** 96.1 ± 6.8 points
- **Aged 10–15 years:** 94.7 ± 7.3 points
- **Aged 15–18 years:** 94.2 ± 8.1 points

These variations were not statistically significant, underscoring a uniformly positive user experience across demographics.

Adverse Events (AEs) and Serious Adverse Events (SAEs)

During the trial, **12 adverse events (AEs)** were reported among **10 participants** (12.3% overall AE incidence). Of these:

- **Device-Related AEs:** Mild skin irritation at sensor sites in 2.5% of participants (resolved without long-term effects).
- **Non-Device-Related AEs:** Respiratory infections and influenza, assessed as unrelated to the device or trial protocol.

No serious adverse events (SAEs) or trial withdrawals due to AEs were reported.

Relationship Between AEs and Device Usage

The device-related AEs, such as skin irritation, were attributed to individual sensitivity rather than sensor

application defects. All device-related issues were self-limiting, requiring minimal intervention. The overall safety profile of the GS1 CGMS was favorable, with no major complications identified.

Effectiveness of the GS1 CGMS in Glycemic Control

The GS1 CGMS demonstrated excellent concordance with reference venous blood glucose measurements:

- **Concordance Rate within 20/20% Error Margin:** 93.9% (surpassing the target value of 65%).
- **95% Confidence Interval (Lower Limit):** 92.5% (exceeding the protocol threshold of 60%).
- **Consensus Error Grid Analysis:** 100% of measurement points fell within Zones A+B (95% CI lower limit: 99.7%).

Discussion

Key Findings and Clinical Relevance

This study demonstrated the robust efficacy, safety, and usability of the GS1 CGMS in pediatric patients aged 3 to under 18 years, highlighting its transformative potential in glycemic monitoring. A concordance rate of 93.9% within the 20/20% error margin significantly surpassed the predefined threshold of 65%, underscoring the device's reliability across all glycemic ranges. Measurements predominantly fell within Clarke and Consensus Error Grid zones A and B, meeting and exceeding international standards for continuous glucose monitoring systems[1,2].

The GS1 CGMS effectively detected critical glycemic events with high sensitivity and specificity for hyperglycemia (89.8% sensitivity, 97.0% specificity) and hypoglycemia (97.6% sensitivity, 87.3% specificity).

Usability and Patient-Centered Design

The usability of the GS1 CGMS was highly rated, with an average satisfaction score of **95.3 ± 7.59 points**, reflecting its intuitive design and ease of use. This is critical for fostering adherence among pediatric patients and their caregivers, where engagement and convenience play pivotal roles. Younger children, who often face cognitive or motor limitations, benefited from the device's ergonomic design and clear instructions. Enhanced usability directly correlates with improved adherence, ensuring consistent use and maximizing clinical benefits[3].

Safety Profile

The GS1 CGMS exhibited a favorable safety profile, with a 12.3% overall adverse event (AE) incidence and no serious adverse events (SAEs). Device-related AEs, including mild skin irritation, accounted for 2.5% of cases and were self-limiting. Compared to benchmarks from similar studies, these metrics highlight the GS1 CGMS's suitability for pediatric use[4,5]. Future iterations incorporating hypoallergenic adhesives could further minimize these reactions, enhancing patient comfort and expanding its usability in sensitive populations.

Comparative Performance

The GS1 CGMS's performance aligns closely with, or even surpasses, other established CGMS technologies such as MiniMed and Dexcom. The Mean Absolute Relative Difference (MARD%) of 8.7%, combined with the consistently high concordance rates, places the device among the most reliable continuous glucose monitoring systems[6,7]. Its superior sensitivity for detecting glycemic extremes positions it as a valuable tool for mitigating both acute and long-term complications associated with pediatric diabetes.

Limitations and Future Directions

This study's single-group design and limited sample size present inherent limitations in generalizing the findings to broader populations. The geographic scope, restricted to specific regions, may not reflect global demographic diversity. Addressing these limitations through larger, multicenter randomized controlled trials would provide stronger evidence to validate these findings. Furthermore, longitudinal studies could elucidate the long-term impact of the GS1 CGMS on reducing diabetes-related complications and improving quality of life.

Future research should also explore technological advancements such as extending sensor longevity, enhancing comfort for younger children, and improving accuracy in extreme glucose ranges. Comparative evaluations with other CGMS devices under identical clinical conditions would further highlight the GS1 CGMS's strengths and areas for optimization.

Clinical Integration and Telemedicine Potential

The GS1 CGMS seamlessly integrates into existing diabetes management protocols, complementing insulin therapies and dietary adjustments. Its real-time glucose monitoring and accurate detection of asymptomatic glycemic events enable proactive clinical interventions, reducing the frequency of in-person consultations and enhancing the feasibility of telemedicine applications. This feature is particularly beneficial for managing pediatric diabetes in remote or underserved areas, ensuring equitable access to advanced glycemic monitoring technologies.

Conclusion

This independent analysis demonstrated that the GS1 Continuous Glucose Monitoring System (CGMS) is a reliable, accurate, and user-friendly solution for pediatric glycemic monitoring. Its ability to provide continuous glucose data and detect asymptomatic glycemic events can significantly enhance diabetes management, leading to improved clinical outcomes and quality of life for pediatric patients. The findings support the integration of the GS1 CGMS into routine pediatric diabetes care. Future research should focus on expanding its applicability, exploring long-term benefits, and conducting comparative studies with other CGMS technologies to further establish its clinical utility.

Conflict of Interest: Author declared that no conflict of interest.

Competing Interest declaration: Author declared that no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethics approval: The trial protocol was submitted to and approved by the Ethics Committees of Beijing Children's Hospital, Capital Medical University (approval date: April 14, 2023), Shenzhen Children's Hospital (approval date: July 14, 2023), and Fujian Medical University Union Hospital (approval date: June 30, 2023). No revisions occurred during the clinical trial.

Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Funding: The trial was sponsored by Shenzhen SiSensing Co., Ltd. (Protocol No. SS-CTP-GS1-0002, Version V1.0, dated February 24, 2023). This independent analysis was conducted using clinical trial data shared by Shenzhen SiSensing Co., Ltd., and its Turkish partner, BMED Pharmaceuticals.

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